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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,559	02/11/2000	Roland Valdes JR.	1160.033US1	6803

21186 7590 03/18/2002
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[REDACTED] EXAMINER

WEBMAN, EDWARD J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1617

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SUPPL.
Office Action Summary

Application No.	09/503559	Applicant(s)	VALDES
Examiner	WEBMAN	Group Art Unit	1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

Responsive to communication(s) filed on 1/3/02

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-34 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) 1-34 is/are objected to.

Application Papers

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

All Some* None of the:

Certified copies of the priority documents have been received.

Certified copies of the priority documents have been received in Application No. _____.

Copies of the certified copies of the priority documents have been received
in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Notice of Reference(s) Cited, PTO-892

Notice of Draftsperson's Patent Drawing Review, PTO-948

Interview Summary, PTO-413

Notice of Informal Patent Application, PTO-152

Other _____

Office Action Summary

In view of and overlooked typing error wherein Group I was listed twice the requirement (modified) is regarded B:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 21-22, drawn to an intermediate compositions, classified in class 53 or 530 respectively, subclass 5 or 387.1 respectively.
- II. Claims 8-9, 23, drawn to a composition, classified in class 424, subclass 423.
- III. Claims 10-20, 24-26, 27-29, 30-34, drawn to methods of using, classified in class 514 or 436 respectively, subclass 869 1+ respectively.

The inventions are distinct, each from the other because:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a reagent for chromatography and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced by a materially different product such as digitoxin for treating heart disease or a Dh-OLF modifying enzyme for an enzyme-based quantitating method respectively.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Should applicants elect Group I or II, the following election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: a factor, a binder for the factor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, compositions are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicants elect Group III, the following elections of species are required:

This application contains claims directed to the following patentably distinct species of the claimed invention: a method of treating a condition, a quantitative method.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, methods of use are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicants elect a method of treating a condition, the following election of species is required:

Claims 11, 12 are generic to a plurality of disclosed patentably distinct species comprising loci of treatment. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 15, 17, 19, 20 are generic to a plurality of disclosed patentably distinct species comprising conditions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicants elect a quantitative method, the following election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: a quantitative method using antibodies, a quantitative method using HPLC.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, quantitative methods are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

A restriction requirement by phone was not attempted in view of the complexity of the requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins can be reached on 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-1235 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Webman: mv
March 13, 2002

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

